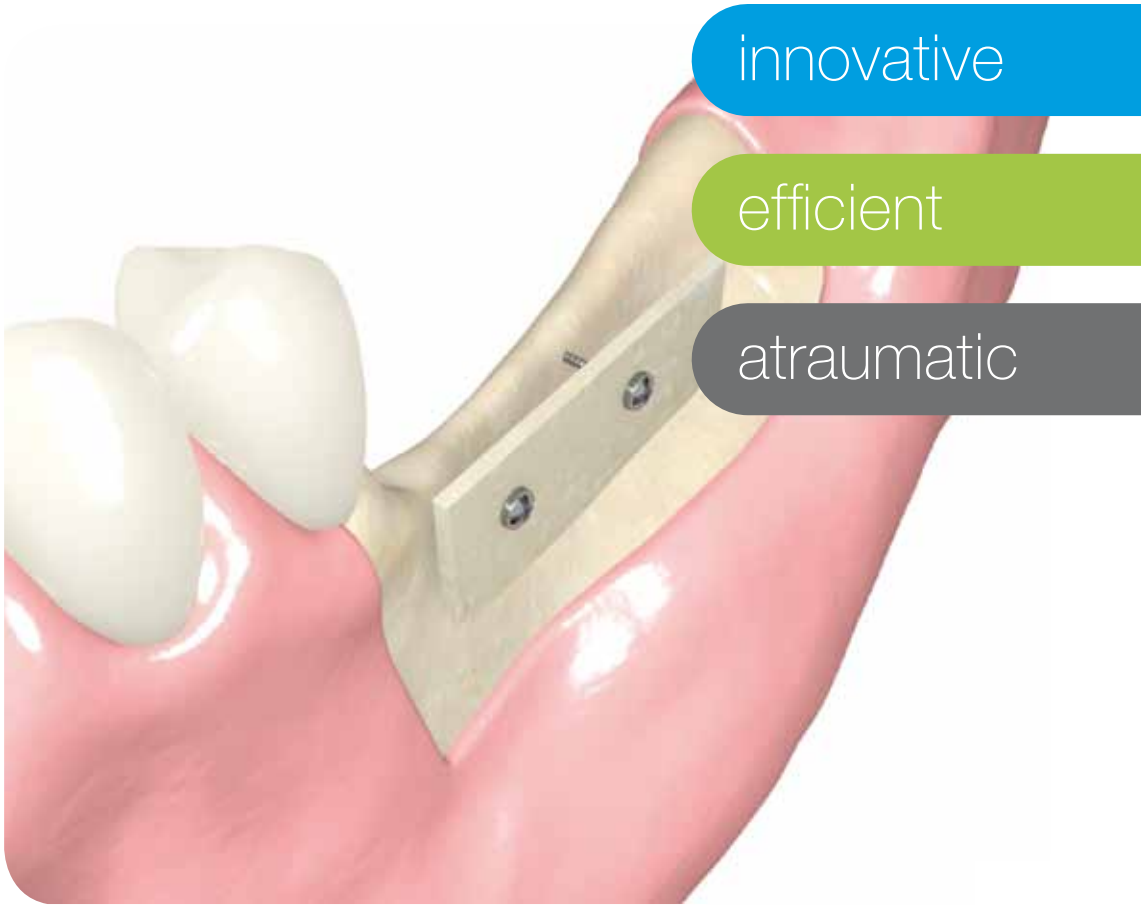
dental
bone & tissue
regeneration

botiss
biomaterials

maxgraft® cortico

Shell technique with allogenic cortical struts

hard tissue

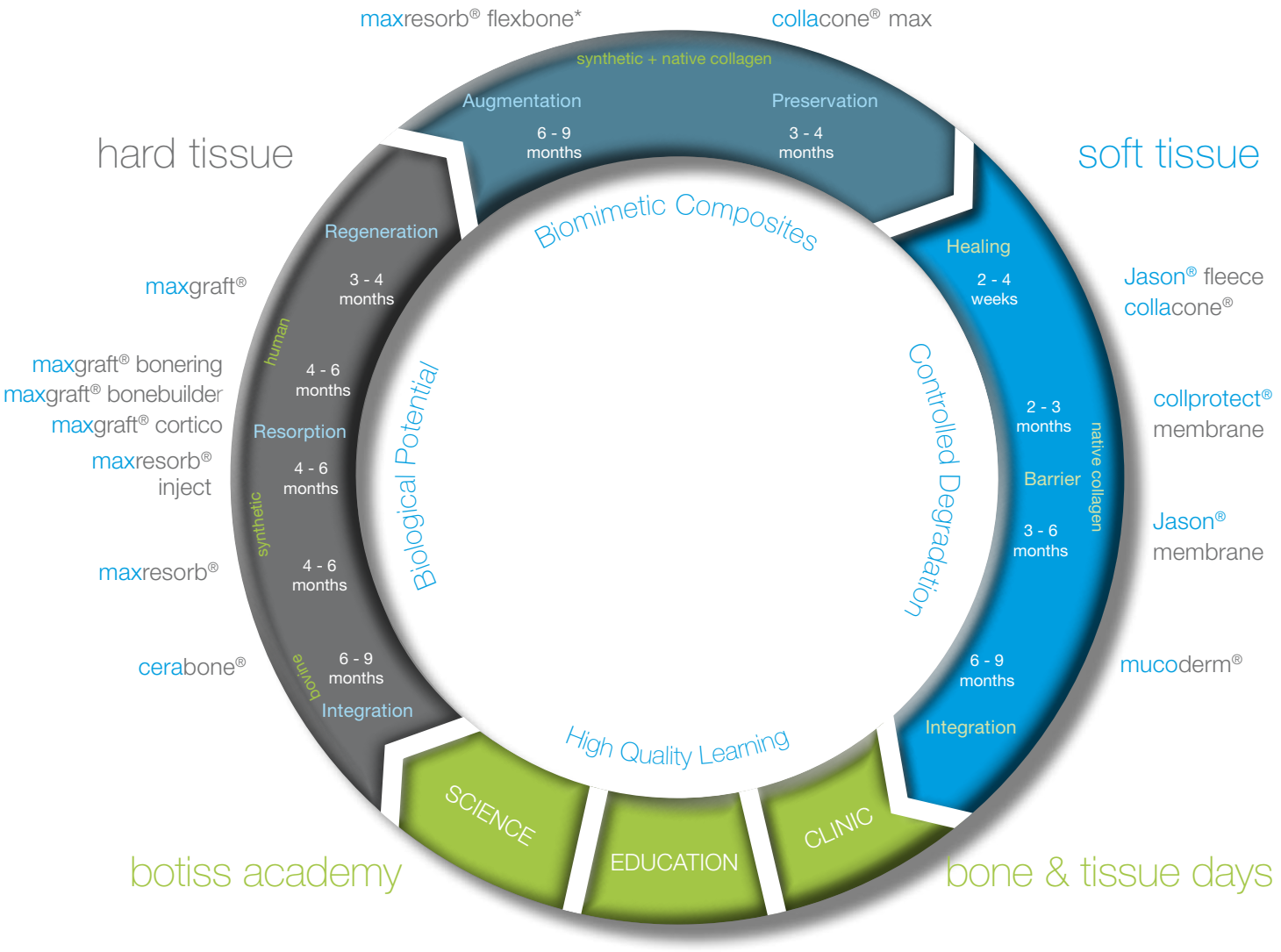


innovative

efficient

atraumatic

botiss regeneration system



cerabone®

Natural bovine bone graft

maxresorb®

Synthetic biphasic calcium phosphate

maxresorb® inject

Synthetic injectable bone paste

maxgraft® bonebuilder

Patient matched allogenic bone implant

maxgraft® bonering / maxgraft® cortico

Processed allogenic bone ring / Processed allogenic bone plate

maxgraft®

Processed allogenic bone graft

collacone® max

Cone
(CaP / Collagen composite)

maxresorb® flexbone*

Flexible blocks
(CaP / Collagen composite)

Jason® fleece / collacone®

Collagenic hemostypt
(Sponge / Cone)

collprotect® membrane

Native collagen membrane

Jason® membrane

Native pericardium
GBR / GTR membrane

mucoderm®

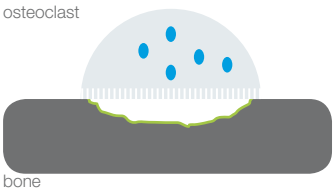
3D-stable soft tissue
(Collagen) graft

* Coming soon

Processed human allograft
Introduction

Various bone graft materials are available to replace and regenerate bone matrix lost by tooth extraction, cystectomy or bone atrophy following loss of teeth or inflammatory processes.
Of all grafting options autologous bone is considered the „gold standard“, because of its biological activity due to vital cells and growth factors.

Yet, the autologous bone from intra-oral donor sites is of restricted quantities and availability, and the bone tissue obtained from the iliac crest is described to be subject to fast resorption. Moreover, the harvesting of autologous bone requires a second surgical site associated with an additional bone defect and potential donor site morbidity. Thus, application of processed allogenic bone tissue appears a sufficient alternative.



New bone formation after grafting with allogenic bone tissue begins with an acute inflammatory response, within which granulation tissue gradually accumulates, and by activation of osteoclasts. The incorporation process begins with the vascularization of the allograft. By activation of osteoclasts the immune system facilitates the remodeling of the graft. These large cells completely degrade medullary bone, thereby allowing its substitution by osteoblasts. The immunological compatibility of processed allogenic bone is not different from autologous tissue. In patients who had allograft surgery, no circulating antibodies could be detected in blood samples[1]. Moreover, several histological studies have well documented that there was no difference in the final stage of incorporation between allograft and autologous graft[2,3].

Classification

Autologous:
- Patient‘s own bone, mostly harvested intra-oraly or from the iliac crest
- Intrinsic biological activity

Allogenic:
- Bone from human donors (multi-organ donors or femoral heads of living donors)
- Natural bone composition and structure

Xenogenic:
- From other organisms, mainly bovine origin
- Long-term volume stability

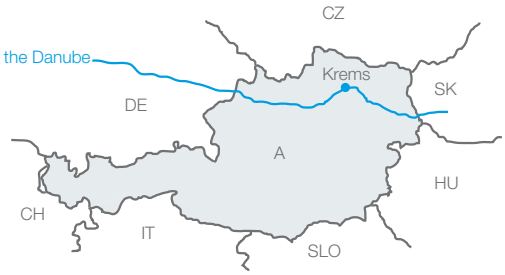
Alloplastic:
- Synthetically produced, preferably calcium phosphate ceramics
- No risk of disease transmission

1. Gomes KU, Carlini JL, Biron C, Rapoport A, Dedivitis RA. Use of allogeneic bone graft in maxillary reconstruction for installation of dental implants. J Oral Maxillofac Surg. 2008 Nov;66(11):2335-8.
2. Urist MR. Bone: Formation by autoinduction. Science 150:893, 1965
3. Urist MR: Bone morphogenetic protein induced bone formation in experimental animals and patients with large bone defects, in Evered D, Barnett S (eds): Cell and Molecular Biology of Vertebrate Hard Tissue. London, CIBA Foundation, 1988

Cells+Tissuebank Austria

C+TBA austria

C+TBA is a non-profit organization aiming to maintain continuous medical supply of allografts under pharmaceutical conditions. Serving as a platform for the definition of safety standards and assurance of compliance with defined product qualities, C+TBA focuses on the specifications of human bone tissue as required in a large number of diseases that are associated with the loss of bone tissue.



C+TBA is certified and audited by the Austrian Ministry of Health in accordance with the European Directives and regulated by the Austrian Tissue Safety Act (GSG 2009).

In Directive 2004/23/EU of March 31th 2004, the European Parliament and the Council of the European Union defined the future general conditions and quality standards for the handling of tissue of human origin, which were further specified in Directives 2006/17/EC and 2006/86/EC. Detailed regulation of the removal, quality control, processing, stockpiling, storage, and distribution of human tissue and cells, provisions have been obligatory for all member states since April 2006. The individual measures are to be undertaken at pharmaceutical level within the framework of a GMP-compliant quality management system.

Tissue donation and procurement

maxgraft® cortico is exclusively produced from bone tissue of multi-organ donors in Austrian hospitals.

The procurement, standardized by a predefined protocol, is carried out by certified procurement centers. All donations are based on highly selective exclusion criteria with regard to the patient's state of health. For all multi-organ donors the highest ethical and safety-related requirements are met.

Donor tissue is only approved for processing after having passed a thorough inspection including a strict serological screening protocol

Serological testing

Virus	Test	Specification
Hepatitis B Virus (HBV)	HBsAg,HBcAb, NAT	negative
Hepatitis C Virus (HCV)	Ab, NAT	negative
Human Immunodeficiency Virus (HIV 1/2)	Ab, NAT	negative
Human T-lymphotropic Virus (HTLV 1/2)	Ab, NAT	negative
Bacteria	**Test**	**Specification**
Treponema pallidum (Lues)	CMIA	negative
Liver parameters	**Test**	**Specification**
ALT/ALAT	serum level	within ref. value

Family members of the deceased are obligated to answer a questionnaire to ensure compliance with the stated exclusion criteria.
After donor acceptance a series of serological testing is performed. In addition to antibody screening (Ab), nucleic acid tests (NAT) are executed to span the diagnostic gap. The serological screening of post-mortem donors has extensively been tested and validated[1].

Blood samples are taken within 24h post-mortem in case of multi-organ donation

1. Kalus U, Wilkemeyer I, Caspari G, Schroeter J, Pruss A. Validation of the Serological Testing for Anti-HIV-1/2, Anti-HCV, HBsAg, and Anti-HBc from Post-mortem Blood on the Siemens-BEP-III Automatic System. Transfusion Medicine and hemotherapy. 2011;38:365-372

The C+TBA cleaning process

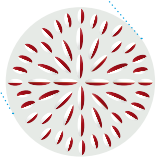
After shaping and crude cleaning, the donor tissue undergoes ultrasonication to remove blood, cells and tissue components, but mainly to promote the removal of fat from the cancellous structure of the bone, improving the penetration of subsequent substances.

During a chemical treatment non-collagenic proteins are denatured, potential viruses are inactivated and bacteria are destroyed. In the subsequent oxidative treatment, persisting soluble proteins are denatured and potential antigenicity is eliminated.

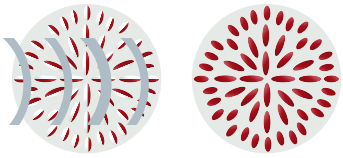
Finally, the tissue undergoes lyophilization, a dehydration technique which facilitates the sublimation of frozen tissue water from solid phase to gas phase, thereby preserving the structural integrity of the material.

The tissue can be reconstituted rapidly due to microscopic pores within the material, which were created by the sublimating ice crystals. It has been well established that the lyophilization process preserves structural properties that improve graft incorporation[1].

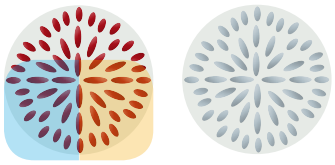
The final sterilization by gamma irradiation guarantees a sterility assurance level (SAL) of 10^{-6} while ensuring structural and functional integrity of the product and its packaging.



Step 1:
After crude removal of surrounding soft tissue, fat and cartilage, the donor tissue is brought into its final shape.

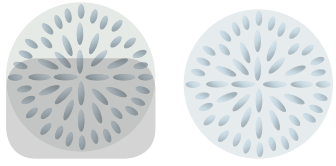


Step 2:
The defatting of the donor tissue allows moderate penetration of solvents during subsequent processing.

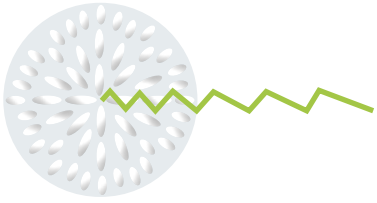


Step 3:
A treatment with alternating durations of diethyl ether and ethanol leaches out cellular components and denatures non-collagenic proteins, thereby inactivating potential viruses.

Step 4:
An oxidative treatment further denatures persisting soluble proteins, thereby eliminating potential antigenicity.



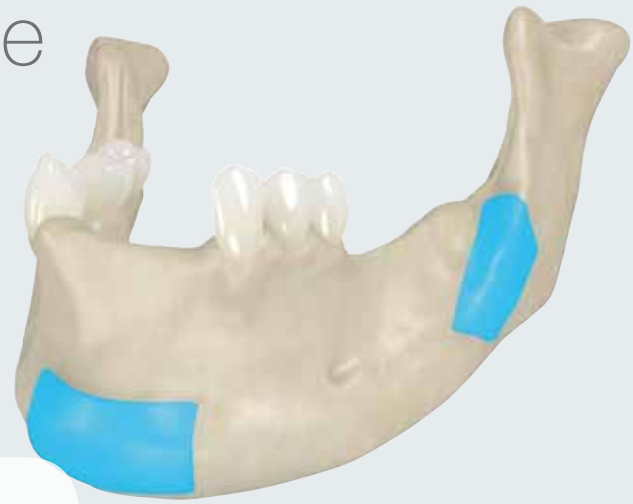
Step 5:
Freeze-drying by lyophilization preserves the natural structure of the tissue and maintains a residual moisture of < 5%, allowing quick rehydration and easy handling.



Step 6:
Double packing and final sterilization by gamma-irradiation guarantees a 5-year shelf-life at room temperature.

1. Osbon DB, Lilly GE, Thompson CW, et al: Bone grafts with surface decalcified allogeneic and particulate autologous bone: Report of cases. J Oral Surg 35:276, 1977

Bone augmentation with the shell technique



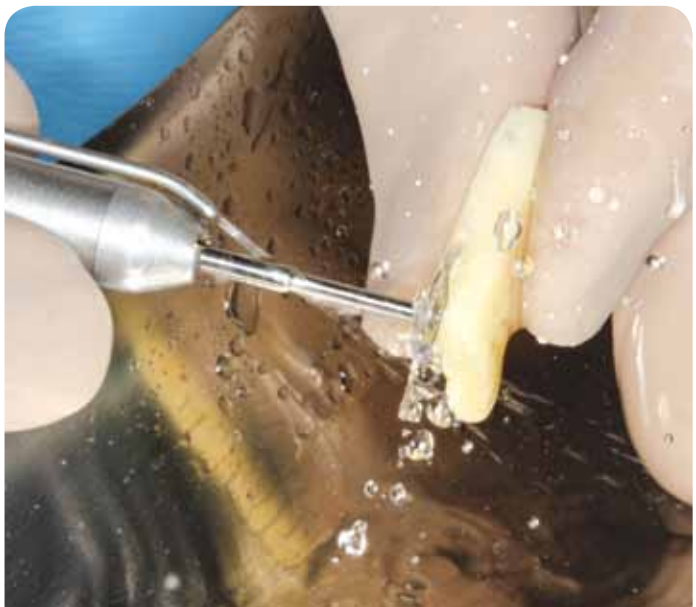
Since decades, autologous bone has been harvested by experienced oral and cranio-maxillo-fascial surgeons.

The transplantation of autologous bone is still the „gold standard“ despite the need of harvesting it from extra- or intraoral donor regions and the need of adaption to the recipient site.
Common donor sites are the oblique line in the retromolar region of the mandible or the chin region[1,2].

Usually a micro saw is used to harvest a bone block that is later split into two to three thin bone plates. These bone plates can further be reduced in thickness with a safescraper or a bone mill. The complete harvesting process is time consuming and often it is more painful for the patient than the augmentation itself and also a possible source of complications.

The concept of the shell technique is the preparation of a biological container which creates the necessary space for the full incorporation of the particulated bone graft material. The osteocytes in the cortical bone die within a few days[3], so the boneplate functions as a stable, avital and slowly resorbable membrane.

Preparation of thin bone plates from a cortical block



1. Khoury F. Chirurgische Aspekte und Ergebnisse zur Verbesserung des Knochenlagers vor implantologischen Maßnahmen. Implantologie.1994;3:237-247
2. Khoury F. Augmentation of the sinus floor with mandibular bone block and simultaneous implantation: a 6 year clinical investigation. Int J Oral Maxillofac Implants 1999;14:557-564
3. Eitel F. et al. Theoretische Grundlagen der Knochentransplantation. in: Hierholzer G, Zilch H; Transplantatlager und Implantatlager bei verschiedenen Operationen. Heidelberg: Springer, 1980:1-12

maxgraft® cortico
The shell technique with allogenic bone plates

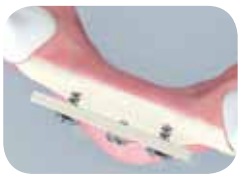
maxgraft® cortico is a prefabricated bone plate made of processed allogenic donor bone and can be used for the shell technique as a substitute for autologous bone.

maxgraft cortico was developed to circumvent donor site morbidity and to prevent the time-consuming harvesting and splitting of autologous bone blocks.

Preparation of the defect


After preparation of the defect, or even before in the digital planning of the operation the required size and position of the plate is determined. Using a diamond disc it can then be trimmed extraorally.

Fixation and adaption


The plate is positioned with a distance by predrilling through plate and local bone and fixation with osteosynthesis screws to create a fixed compartment. To prevent perforations of the soft tissue, sharp edges need to be removed, e.g. by using a diamond ball.

Filling of the defect



The space between local bone and cortical plate can be filled with a variety of different particulated bone grafting materials. Afterwards, the augmentation area needs to be covered with a barrier membrane (Jason® membrane, collprotect® membrane) and closed tension free and saliva proof.

Indications

- Vertical augmentation
- Horizontal augmentation
- Complex three-dimensional augmentations
- Single tooth gaps
- Sinus floor elevation
- Fenestration defects

Properties

- Osteoconductive
- Natural and controlled remodeling
- Preserved biomechanical parameters
- Sterile without antigenic effects
- Five years shelf life

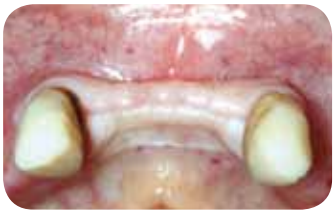
maxgraft®

To fascilitate osteosynthesis, allogenic particles (e.g. maxgraft®) can be used to fill the defect. The preserved human collagen provides excellent osteoconductivity and enables complete remodelling. Mixing with autologous chips or particulated PRF matrizes can support the ossification.

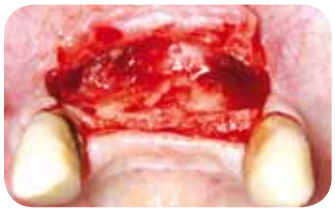
Clinical application

Clinical case Jan Kielhorn, Oehringen, Germany

Frontal defect treated with maxgraft® cortico

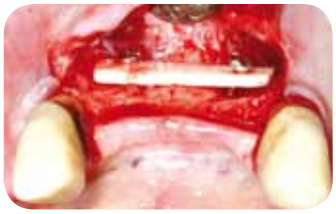


Severe atrophy in the esthetic region

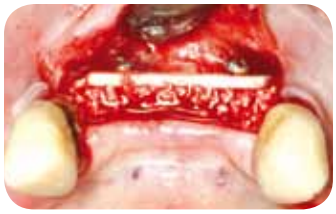


Preparation of the defect

maxgraft® cortico in preparation



Fixation with osteosynthesis screws



Augmentation with cerabone®

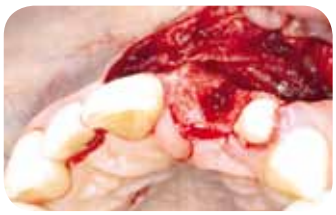
Covering with Jason® membrane and saliva-proof wound closure

Rehydration

The processing of the C⁺TBA products preserves the natural collagen and maintains a residual moisture of <5%. According to our clinical users rehydration is not necessary and the products are ready for immediate use.

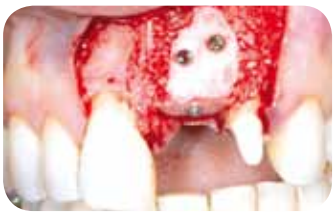
Clinical case Dr. Krzystof Chmielewski, Gdansk, Poland

Single tooth restauration with maxgraft® cortico

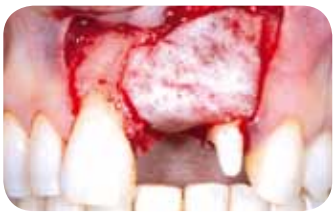


Single tooth defect with severely resorbed vestibular wall

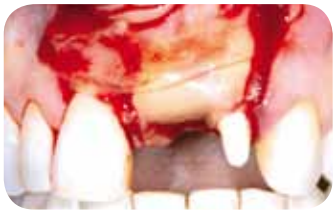
Fixation of maxgraft® cortico using an osteosynthesis screw



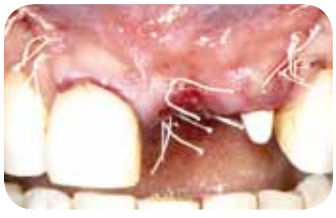
Augmentation with maxgraft®, granules mixed with particulated PRF matrizes and fixation of a second maxgraft® cortico



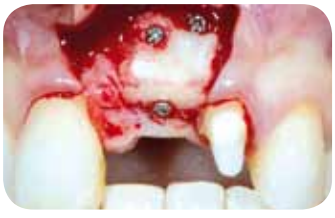
Covering of the augmentation area with Jason® membrane



Covering with a PRF matrix for improved soft tissue healing



Tension-free wound closure



Situation after a healing period of four and a half months

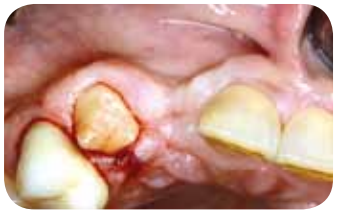
Stable implantation

Clinical application

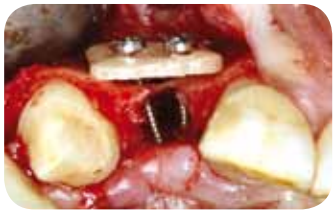
Clinical case

Dr. Uwe Radmacher, Mannheim, Germany

Single tooth restauration with maxgraft® cortico



Clinical situation

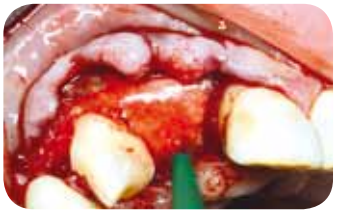


Fixation of maxgraft® cortico

Augmentation with a mix of autologous chips and cerabone®

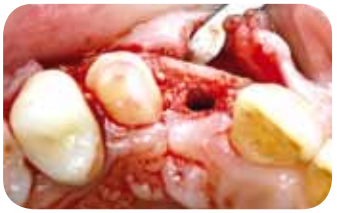
Advantages

- Established technique
- Significant reduction of operation time
- No donor site morbidity
- No limitation of grafting material

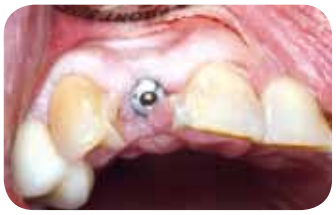


Covering with Jason® membrane

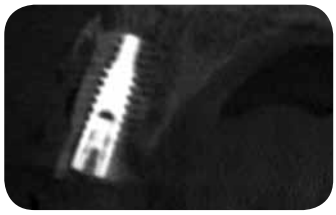
Tension-free wound closure



After the healing period of four months



Augmentation area after healing and removal of the provisionals



Implant position after healing

Product Specifications

maxgraft® cortico

Art.-No.		Content
31251	cortical strut 25 x 10 x 1 mm	1 x
	cortical strut 25 x 10 x 1 mm	3 x 1

maxgraft® bonebuilder

Art.-No.	Content
PMIa	Individual planning and production of a bone transplant max. dimensions 23 x 13 x 13 mm

maxgraft® bonering (Height 10 mm)

Art.-No.	Dimension	Content
33170	height 10 mm, Ø 7 mm	1 x cancellous ring
33160	height 10 mm, Ø 6 mm	1 x cancellous ring

Recommended for implant diameters from 3.3 - 3.6 mm

maxgraft® cancellous granules

Art.-No.	Particle Size	Content
30005	< 2.0 mm	1 x 0.5 ml
30010	< 2.0 mm	1 x 1.0 ml
30020	< 2.0 mm	1 x 2.0 ml
30040	< 2.0 mm	1 x 4.0 ml

maxgraft® cortico-cancellous granules

Art.-No.	Particle Size	Content
31005	< 2.0 mm	1 x 0.5 ml
31010	< 2.0 mm	1 x 1.0 ml
31020	< 2.0 mm	1 x 2.0 ml
31040	< 2.0 mm	1 x 4.0 ml

maxgraft® blocks

Art.-No.	Particle Size	Content
32111	cancellous, 10 x 10 x 10 mm	1 x block
32112	cancellous, 20 x 10 x 10 mm	1 x block

maxgraft® bonebuilder dummy

Art.-No.	Content
32100	Individual 3D-printed model of the patient`s defect and the planned bonebuilder for demonstration purposes made of plastic

bonering fix

Art.-No.	Content	
33010	bonering fix	1 x

maxgraft® bonering surgical kit

Art.-No.	Content
33000	1 x trephine 7 mm 1 x trephine 6 mm 1 x planator 7 mm 1 x planator 6 mm 1 x diamond disc 10 mm 1 x diamond tulip 3 mm

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